STATE MEDICAID P&T COMMITTEE MEETING

FRIDAY, December 21, 2007
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Committee Members Present:

Lowry Bushnell, M.D.
Karen Gunning, Pharm. D.
Raymond Ward, M.D.
Koby Taylor, Pharm D.
Kort DeLost, R.Ph.
Jerome Wohleb, Pharm D.
Duane Parke, R.Ph.

Board Members Excused:

David Harris, M.D.
Thomas Miller, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:

RaeDell Ashley
Jennifer Zeleny
Lisa Hulbert

University of Utah Drug Information Center Staff Present:

Chris Beckwith, Pharm. D.
Linda Tyler, Pharm. D.
John Vu

Other Individuals Present:

Slater Sparks, Sciele Pharma
Kurt Steinbridge, GSK
Tom Sanders, U of U
David Nilson, GSK
Barbara Boner, Novartis
Jay Jennings, Sanofi-Aventis
Amanda Gallegos, U of U
David Browning, GSK
Joann Ginal, BMS
Wayne Roberts, U of U

Meeting conducted by: Raymond Ward, M.D., Co-Chairperson.

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1. Minutes for November 2007 were reviewed. Duane Parke made a motion to approve the minutes. The motion was seconded by Kort DeLost. The motion passed with a unanimous vote by Dr. Ward, Dr. Taylor, Dr. Bushnell, Kort DeLost, and Duane Parke.

2. DUR Board Update: Tim Morley addressed the Committee. The DUR Board plans to take up issues after they come through the P&T Committee for discussion. In the coming month, in January the DUR Board plans to take up oral hypoglycemics and antidiabetic agents. The DUR Board plans to continue to work closely with the P&T Committee and follow up on Committee actions.

3. Antihypertensives - Beta Blockers: Dr. Beckwith addressed the Committee. There are 14 beta blockers that were included in the information that the University of Utah put together. There are 12 that are strictly beta-selective. The Committee was provided with a table of all of the available agents. The table basically lists which products are available, whether or not there is a generic, and the dosage forms available. There are two products that are both alpha and beta agonistic blockers: labetalol and carvedilol. The one drug that is not on the chart is a new drug called mebivolol or Bistolic. It was approved this week for hypertension. It is another beta-one selective agents. It is not available generically. It is a once-daily product for hypertension. The Oregon monograph for the beta-adrenergic blockers picked the agents that they will include in the monograph. They actually included 16 agents in the monograph. They counted extended-release and immediate-release products as separate products. They did have one product, cartevolol, that is only available as an opthalmic agent in the U.S. They laid out specific indications that they would evaluate: hypertension, angina, coronary artery bypass grafts, recent MI, heart failure, atrial arrhythmia, migraine, and bleeding esophageal varices. They evaluated those indications for specific outcomes. They tried to look at real-world outcomes, such as all cause mortality, organ damage, exercise tolerance, hospitalizations, etc. rather than just measuring blood pressure or heart rate as endpoints. The broke down the indications into several key questions. The first key question is do the beta-blockers differ in efficacy for the indication of hypertension? The beta-blockers are equally effective in controlling blood pressure. For long-term outcomes there are no head-to-head trials that have been conducted between the agents. When compared with diuretics, they are generally less effective. In some cases, they were no better than placebo in reducing cardiovascular events. There was one trial that showed that metoprolol reduced all-cause mortality as compared to the thiazides. There was no evidence that one agent was better than the other in improving quality of life.

For adults with angina, are there any differences in efficacy? In trials that compared carvedilol, metroprolol; pindolol versus propranolol; betaxolol versus propranolol there were no differences exercise tolerance or plaque frequency. In specific patient subgroups, such as patients with angina, COPD, atenolol and bisoprolol were equally effective. In patients with angina and hypertension, atenolol and labetalol were equally effective. The one point to pull out of this is that beta-blockers with intrinsic sympathomimetic activity are actually not recommended in patients with angina. Those would be agents like acebutolol, panbutolol, or pindolol. In general with beta-blockers, efficacy may decrease over the long term. For patients with angina, propranolol was more effective for patients than placebo for 8 weeks in one trial, but at 24 weeks it had similar efficacy to placebo.

For patients with CABG do they differ in efficacy? There are no head-to-head comparative trials. In other trials that just evaluated long-term use of a beta-blocker, they did not improve mortality or other outcomes. In fact, with metoprolol versus placebo, mortality was 3.3% with metoprolol and 1.8% with placebo. That trial may have lacked some power to detect ischemic events, but in general there does not seem to be a difference from placebo.

In patients with an MI do they differ in efficacy? From the available trials, they were not available to make a determination. There are primarily indirect comparisons, which make it difficult to draw any conclusions. As far as overall mortality, the outcomes are really mixed in patients who have had MI. Some of the trials have shown that the agents reduce mortality, reduce sudden death, or myocardial infarction, but other trials show that there is either no effect or an insignificant effect. The agents that have primarily been evaluated for this are acebutolol, carvedilol, metoprolol, propranolol, and timolol.

In patients with heart failure is there a difference in efficacy? There have been very few head-to-head trials and most of them lacked the power to detect the effects. The one that did have enough power is the COMET trial, which compared carvedilol to metoprolol, and found that carvedilol was more effective than metoprolol for reducing all-cause mortality, cardiovascular mortality, sudden death, and stroke. However, the two agents were equivalent in reducing the overall endpoint of mortality and hospitalization, death secondary to circulatory failure, other cardiovascular death, and days with decreased well-being. In placebo-controlled trials, bisoprolol, long-acting metoprolol, and carvedilol have all been shown to reduce mortality and sudden cardiovascular death in patients with heart failure.

In patients with atrial arrhythmia, do they differ in efficacy? There is one head-to-head trial that compared bisoprolol with carvedilol. They showed equivalent efficacy as far as patients that relapsed with atrial fibrillation. Atenolol, nadolol, and pindolol have also been evaluated for this disorder, and they were more effective than placebo, although they were not compares with each other.

In migraines do they differ in efficacy? Five head-to-head trials found no difference between the agents. The comparisons that were made were metoprolol, atenolol, and timolol, versus propranolol, and those were equivalent.

For patients with bleeding esophageal varices do they differ in efficacy? One head-to-head trial compared atenolol and propranolol and found no difference in rates of re-bleeding or all-cause mortality. That is the only comparison available. There are some placebo-controlled trials with immediate release versus extended release propranolol, but they do not give any additional information to make any comparison. The only other information that is out there is that propranolol may be more effective with late initiation in this disorder.

Do they differ in safety or efficacy? Some of the trials found differences in a specific adverse event, but looking at the entire body of evidence, there are very few differences between the agents an no one stands out as being safer or more effective. They have similar rates of discontinuation due to adverse events, similar rates of bardycardia, similar rates of hypotension. One trial found that carvedilol caused more dizziness than metoprolol, but there may have been some issues with how they defined dizziness. They were other trials that found no difference between these two agents. There is a retrospective analysis that shows that patients treated with metoprolol are more likely to develop new-onset diabetes than those taking carvedilol. That was a post-hoc analysis, and looking at the confidence intervals, the rate with metoprolol was 10.1% and the rate with carvedilol was 8.7% and the 95% confidence interval for the hazard ratio was 0.61 to 0.997. Depending on how the numbers are evaluated, they barely achieved statistical significance. This was also a retrospective analysis, so there are some real questions as to whether that was, in fact, a true effect or not.

The last key question was are there subgroups of patients for whom one agent is more effective or safer? There is no data to suggest that there are differences in the agents based on demographics such as age, gender, or other disease states such as diabetes.

The University of Utah has provided supplemental information. The Committee had asked for information comparing the safety and efficacy of extended-release versus immediate release carvedilol, and whether there were any trials evaluating those. The immediate-release carvedilol is actually available in a generic. Carvedilol extended-release product is only

available as a branded product. The agents share the same indications for both dosage forms. There are no published clinical trials that directly compare the two agents. Looking at the FDA approval of the extended-release product, that was based on studies established as bioequivalent with the immediate release. There are some kinetic studies that have been conducted, and they found that beta-blocking activity were similar between the two doses.

The Committee had asked if there are differences in CNS side-effects between the beta-blockers. John Vu addressed the Committee. All of the beta-blockers have some CNS effects reported with them, including sleep disturbances, drowsiness, fatigue, and hallucinations. There are some agents that have higher lipophilicity than other agents. Some of the studies have shown that with higher lipophilicity there have been higher concentrations in the brain. The goal was to see if there was a relationship between increased lipid solubility and increased side-effects. Table 1 in the handouts shows the different degrees of lipid solubility in the agents. A Medline search returned 14 trials on the topic. 6 of these trials showed no difference between the agents. In the studies that showed no difference, they generally used a common CNS endpoint. There were 4 studies that did show a difference between agents that were considered high lipophilicity versus atenolol. However, these studies used different CNS endpoints. There is no clear association between lipophilicity and increased CNS side effects. The studies that did show a difference showed that there may be potential benefit in patients who have reported CNS side-effects before, if they convert over to an agent that is less lipid soluble, they may benefit from less CNS side-effects.

David Nilson from GlaxoSmithKline addressed the Committee. Coreg CR is a once-a-day formulation of Coreg. Coreg CR is differentiated from other once daily beta blockers in that its mechanism of action includes triple blockade, blocking the beta-1, beta-2, and alpha-adrenergic receptors. Coreg CR was recently approved by the FDA for the same indications as Coreg, namely to severe heart failure, to reduce cardiovascular mortality in patients who are post-MI with left ventricular dysfunction and essential hypertension. The Gemini trial was a head-to-head hypertension trial in type 2 diabetic patients against metoprolol tartrate. The primary endpoint was changes in hemoglobin A1C. There was a statistically significant increase in hemoglobin A1C with metoprolol and no change with Coreg. Recently, the American Association of Clinical Endocrinologists has recommended Coreg as a preferred beta-blocker among diabetic patients due to its neutral effect on hemoglobin A1C parameters compared with beta-1 selective blockade alone. The basis for this recommendation was data reported in the Gemini study, and the data has recently been incorporated into the prescribing information. In patients with left ventricular dysfunction following myocardial infarction, the Capricorn trial was a placebo-controlled trial in patients who had experienced MI and who had an ejection fraction of < 40%. The study demonstrated that Coreg reduced mortality by 23%. The Capricorn study also demonstrated that patients treated with Coreg had a 40% decrease in recurrent fatal or non-fatal MI. These data were recently added to the prescribing information for Coreg and Coreg CR. Coreg CR is also indicated for the treatment of mild to severe heart failure. In the Comet trial, Coreg decreased all cause mortality by 17% compared to metoprolol. A recently published analysis of the Comet study also demonstrated that Coreg also decreased cardiovascular mortality by 20%, decreased sudden death by 19%, and decreased death due to stroke by 67%. These data were recently also added to the prescribing information. The benefits of a drug taken once versus twice daily include better compliance. Studies have shown that decreasing the number of doses taken per day increases patient compliance with medication. Increased adherence to beta-blockers, including Coreg, is correlated with better outcomes. In the Behat trial beta-blocker study in

post-MI patients, those who took less than 75% of there prescribed medications had a 2.6 fold increase in mortality risk during the first year post-MI. In the earlier heart failure studies with Coreg, a dose response study called MOCHA demonstrated dose-related benefits with regard to ejection fraction improvements, mortality, and hospitalization of patients achieving optimal target doses of Coreg. Patients who are adherent to their medications are more likely to achieve beneficial target doses, which leads to better outcomes. Finally, an analysis of adherence data in Coreg in patients with heart failure or post-MI with LVD demonstrated that for every 10% increase in adherence, the risk for cardiovascular and all-cause hospitalizations were decreased by 9%. Additionally cardiovascular and all-cause costs were decreased by 6% and 4% respectively for every 10% increase in adherence. In general, the adverse event profiles for BID Coreg and Coreg CR are similar. However, in hypertension trials, Coreg CR was associated with lower incidence of adverse events, especially headache, which may lead to better tolerability of the once-daily formulation. The most common adverse events include dizziness, fatigue, weight gain, hypotension, and bardycardia. Coreg CR has similar contra-indications as other beta-blockers, including second or third degree AV block, sick sinus syndrome, or bardycardia, unless a permanent pace maker is in place, or in patients with cardiogenic shock, or in patients with decompensated heart failure requiring use of intravenous innotropic therapy. Coreg CR blocks the beta-2 receptor, as well as alpha and beta-1. This confers therapeutic benefits over other beta-blockers, especially in heart failure. However, because of the beta-2 blockade, Coreg CR is contraindicated in patients with bronchial asthma or related bronchiospastic conditions. Coreg CR is now available as a once-daily formulation, which would be an important addition to the formulary to help patients in Utah remain more compliant with treatment. The Committee is asked to consider Coreg CR for inclusion on the PDL.

Dr. Ward asked about cost. Most beta blockers are very inexpensive. Carvedilol has come down considerably with the availability of the generic. The Division can provide data many different ways, but cannot provide secondary rebate information, as it is confidential. Because some of the data provided by the Division has been provided from a time period before a generic was available, the cost data on the handouts may not reflect actual costs of generics currently available.

Dr. Bushnell stated that he sees serious problems with fatigue and depression in the agents that have a higher penetration. He would like to see at least atenolol available as one alternative on the PDL.

Karen Gunning stated that her experience is that QD versus BID dosing does not have a large effect on compliance. Only in TID or QID dosing does that effect get borne out. She asked Dr. Beckwith if their analysis confirmed this. Dr. Beckwith stated that the University was not able to examine this. The other Committee members did not feel that the additional cost of brand versus generic justified QD versus BID dosing.

The Committee felt that there is no substantial difference on safety or efficacy that would compel them to recommend a branded product. Acceptable alternatives for the PDL exist from the generics that are available. Non-generic agents include Carvedilol CR, penbutolol, Innopran XL.

Jerome made a motion to recommend that the Department that the specific branded products not be included on the PDL. Dr. Bushnell seconded the motion. The motion passed unanimously by Duane Parke, Kort DeLost, Koby Taylor, Dr. Ward, Dr. Bushnell, Karen

Gunning, and Jerome Wohleb.

Jerome Wohleb asked if there was any information available about the new beta-blocker that is coming to market. It was just approved Tuesday. It is a once-daily beta-blocker. It is not cardioselective. It is only indicated for hypertension. The trials that they took to the FDA for approval were all placebo controlled. There were some comparisons between this agent and other beta-blockers for hypertension. It was also evaluated for heart failure and left ventricular dysfunction. It looks like there is a very similar scope of literature for this agent. The University did not have a chance to evaluate those studies, but from glancing at it, it doesn't appear to be significantly different from any other available beta-blockers.

4. Antihypertensives - Calcium Channel Blockers: Linda Tyler addressed the Commitee. The Oregon document is relatively complete. The University of Utah Drug Information Service prepared two supplemental handouts, which were provided to the Committee. The main actions of calcium channel blockers include dilitation of the coronary and peripheral vasculature, and negative inotropic action, reduction of heart rate, and slowing of AV conduction. The effects of individual drugs vary by their degrees of selectivity at the different tissue sites and the baroreceptor responses to the vasodilitation caused by calcium channel blockers. Calcium channel blockers are generally classed by three groups, but there is a tendency to talk about them as two groups. The dihydropyridines include amlodipine, felodipine, isradapine, nicardipine, nifedipine, nimodipine, and nisoldipine. Beperdil was included in the review, but is no longer on the market in the United States. The non-dihydropyridines diltiazem and verapamil. Dihydropyridines are considered to have greater selectivity for vascular smooth muscle than for myocardium. They seem to have less negative inotropic effects than verapamil and diltiazem. It is unclear if this translates into clinical differences. The scope of the key questions that were addressed by the Oregon document are: Are there key differences in the effectiveness in general? Are there differences in adverse events? Are there any issues in special populations that need to be considered? The indications that they looked at were hypertension, angina, ventricular tachycardia, and systolic dysfunction. For each of these indications, they then went on to look at calcium channel blockers compared to calcium channel blockers, calcium channel blockers compared to other interventions, and calcium channel blockers compared to placebo. The review tried to focus on what the key outcomes were, including all cause mortality, cardiovascular mortality, cardiac events, quality of life, development of renal failure, and stroke. Many of the drugs and many of the studies just look at hypertension, which is considered an intermediate surrogate endpoint.

The first key question is do calcium channel blockers differ in effectiveness in the treatment of adult patients with essential hypertension, angina, supraventricular arrhythmias, or systolic dysfunction? The first questions was specifically around hypertension in comparing calcium channel blockers to calcium channel blockers. All significantly lowered blood pressure. Outcomes were not really addressed in these studies, only hypertension. As such, it was difficult to tell if there were any significant differences in the agents in terms of efficacy. There is a discussion of calcium channel blockers compared to other therapies. One of the observations of the Oregon review was that it was impossible to compare these studies because the titration schedules varied so widely between the studies, and because each of the studies allowed for different administration of additional agents, and none of the studies reported the outcome of interest. There were 5 tables in the study to look at issues related to outcomes. Were there differences in mortality? Were there differences in cardiovascular disease? Were there different outcomes in myocardial infarction? For the first two, there

were no differences found between the agents, and with other agents outside of the class. Looking at myocardial infarction, amlodipine had slightly less myocardial infarctions, but still statistically significant compared to valsartan or irbesartan. In table 4 they compared stroke, and no differences were found. In table 5 they compared heart failure, and amlodipine had a statistically significant increase in heart failure when compared to rovesartan and chlorthalidone. Likewise, nifedipine had a statistically significant higher rate of heart failure when compared to co-amiloride and hydrochlorothiazide. In summary, calcium channel blockers performed no better than diuretics or beta blockers for all health outcomes. In direct comparisons, calcium channel blockers showed no differences among calcium channel blockers. In studies comparing non-dihydropyridines to beta blockers or diuretics, no statistically significant differences were documented.

Are there differences in effectiveness in angina? In comparing calcium channel blockers to calcium channel blockers, only 4 of the calcium channel blockers were evaluated: amlodipine, diltiazem, nicardipine, and nifedipine. No outcomes were reported in these studies. Likewise, the studies were not long enough to make determinations. For the little bit of data available, no discernable differences were identified. In looking at the dihydropyridines versus non-dihydropyridines, there were 6 head-to-head trials for angina. Four looked at dihydropyridnes, and two looked at non-dihydropyridines, and no differences were found in the number of angina attacks, use of nitroglycerine, or time to onset of chest pains with exercise. Comparing the risk differences in the studies, no differences were found in the effectiveness.

Do calcium channel blockers differ in their effectiveness in the treatment of supraventricular tachycardia? In looking at just the calcium channel blockers versus calcium channel blockers, the studies were evaluated for immediate release and sustained release diltiazem and verapamil. Verapamil appeared slightly better, but there were no statistically significant differences in these.

Were there any differences for systolic dysfunction? There were no differences that compared calcium channel blockers to calcium channel blockers.

Do calcium channel blockers differ in safety or adverse effects in the treatment of adult patients? They actually broke this up with patients who were treated with hypertension and angina, and looked at it in that regard. Looking at differences in treating patients with hypertension, there were no head-to-head studies designed to assess the adverse effects of calcium channel blockers. The most common adverse effects that occur with calcium channel blockers are dizziness, edema, and headache. One of the things that they looked at in these studies were differences in cancers. After calcium channel blockers had been on the market for a while, there were studies coming out in the late 80's and early 90's looking at the rates of cancer with calcium channel blockers. There were no differences in the rate of cancers when comparing amlodipine, diuretics, and ace inhibitors. Looking at the onset of new diabetic cases, patients on calcium channel blockers seem to have a lower incidence of onset of new diabetes. The three blockers that were looked at were amlodipine, nifedipine, and diltiazem. Looking at angina, while there were some differences in the withdrawal rates, there were no statistically significant differences for this indication. In studies that looked at peripheral edema, amlodipine seemed to have similar peripheral edema with diltiazem, diltiazem had less peripheral edema than nislodipine, and amlodipine had less peripheral edema than nislodipine. These are the only ones that were looked at. For adverse effects related to supraventricular tachycardia, the trials that were done were of short duration (less

than 7 days), so Oregon felt that there was nothing worthy to discuss. For systolic dysfunction, there were really no studies on adverse effects that brought new information. Looking at dihydropyridines versus non-dihydropyridines, diltiazem seemed to have less peripheral edema than amlodipine and nislodipine, but peripheral edema was not reported in many of the trials, especially in some of the earlier trials of non-dihydropyridines.

In the adverse effects section, key question 2b looked specifically at cancer. There were some trials that showed that there was increased cancer with verapamil and nifedipine that was significant. Digging deeper, it showed that this was a dose-dependant risk. Some of the other trials showed that there was increased risk with verapamil, but not with nifedipine, diltiazem, or amlodipine, and only if it was used for > 2 years. There is another study that showed that there was an increased risk of colon cancer or kidney cancer, but only with use > 5 years. Some other trials showed that there was no increased risk. The available data suggests that there may be some relationship with dose dependancy or with duration of use. Likewise, breast cancer was specifically looked at in some of the trials looking at immediate release non-dihydropyridines, and found that there was an increased risk of breast cancer compared to non-users of any antihypertensive drugs. However, in another trial that looked at duration and immediate release versus delayed release, no statistically significant differences were shown. Table 10 looks at some of the differences in mortality. There are really no differences shown in mortality with diltiazem, nifedipine, amlodipine, or verapamil. Long acting seemed to have less mortality than the short acting formulations in one of the trials, yet another trial showed the exact opposite. Some of these studies lump together dihydropyridines versus non-dihydropyridines, and this is broken out in the table.

The Committee asked specifically if the utilization data provided by Medicaid on the nifedipine combined both long and short acting dose formulations together, since the FDA did put a moratorium on use of short-acting nifedipine for hypertensive emergencies and urgencies. Duane Parke stated that it would be possible to break out utilization of long-acting versus short-acting dosage forms in the future. Dr. Tyler added that this particular use of nifedipine was not covered, and intended for use in difference circumstances. The Committee wondered why Medicaid would even need to have short-acting nifedipine available, outside of uses in pregnancy or pediatrics.

The last set of key questions is around whether there are any differences in special populations. The summary table at the end of the report has a good summary of this. Amlodipine, nicardipine, nifedipine, nislodipine, and verapamil extended release, there was insufficient data to differentiate any calcium channel blockers for adverse events in any one subgroup that were looked at, which included diabetics, patients with renal insufficiency, patients with coronary artery disease, and older generations of patients for hypertension. Likewise, with angina and supraventricular tachycardia, there are no differences. There are very few differences between calcium channel blockers, though different patients may do better on different agents.

Dr. Ward asked the pharmacists what products are available as brands versus generics, particularly with diltiazem formulations, which are confusing. Karen Gunning agreed that this is a huge source of error, and asked that the P&T Committee consider what can be done to reduce potential sources of error. Dr. Tyler stated that the Drug Information Service prepared a table outlining the various formulations that are available and how they are AB-rated with respect to one another. The sustained-release products pose some special issues, since all of these use different methodologies in creating the sustained-release characteristics.

There are also formulations that are 12-hour and 24-hour sustained release formulations. Karen asked the community pharmacists on the Committee if it would be effective to have the Committee recommend one 24-hour formulation for coverage on the PDL. Kort did not feel that this would solve all of the problems, and stated that it is just easier for the prescriber to write the branded name of the diltiazem formulation that he or she desires, so that the pharmacist is clear on which AB-rated product can be substituted. Karen pointed out that some electronic prescribing systems, such as the ones used at the University, automatically switch the prescription to the generic name on the form that is printed, so that suggestion cannot always be followed. Dr. Tyler stated that hospitals such as the University of Utah has some options, such as limiting what products are covered in-house. In a community setting, this is not an option, so it is more challenging to see how to formulate a solution.

Dr. Ward asked if there are any significant cost-differences among the calcium channel blockers, and what products are available as brands versus generics. Medicaid had not provided cost data for all of the individual agents in this class. While the calcium channel blocker products that are available as generics are usually more costly than some of the generic beta-blockers, this is still a very cost-effective category for generic products. Some of the products that are not available as generics, such as Cardizem LA and some of the branded Verapamil products, are quite costly. Some of the newly available generics, such as amlodipine, are rapidly falling in cost.

Dr. Ward asked if it would be appropriate to make a similar motion to what was made with the beta-blockers, that including all of the available generic products would be sufficient for the PDL. Karen Gunning stated that an exception be made for nimodipine, since that has a niche use for subdural hematoma that is not covered by the other calcium channel blockers.

Because the P&T Committee was interested in knowing the cost of the various available agents with respect to one another, Duane Parke said that he will provide this for future meetings. He will also provide data for shorter periods of time (3 months instead of 1 year) so that cost differences in newly available generic products are better visible. Dr. Taylor mentioned that he has seen prescriptions with "Medically Necessary - Dispense as Written", and was curious to see how many time this override is being used. This will be provided to the Committee at a future meeting.

Dr. Tyler suggested that it may be appropriate for the state to limit products with many available generics to just the one most cost-effective products. In the case of diltiazem, the state does not need to cover 20+ different generics, and it may provide an opportunity to reduce potential medication errors by reducing the number of agents that are covered. Karen Gunning stated that there needs to at least be one available dihydropyridine, and one or both non-dihydropyridines.

The community pharmacists felt that restricting the generics that are covered to one brand would open a can of worms, since many of the chains and wholesalers buy on bids for the most cost-effective generics that are available. This may be inconsistent with the most cost-effective generic for Medicaid. Restricting coverage to one generic is also not an insurance industry standard. Having Medicaid do so would impose an unreasonable hardship on community pharmacies who may then be forced to carry multiple companies' generics for a particular product.

The Committee asked if there is a MAC set on the diltiazem products. There is not a Utah

MAC, though one can be set in the future. There may be a Federal MAC, but Duane is uncertain whether or not there is one, or what it is. Dr. Wohleb suggested that a MAC may assist Medicaid with saving money on this drug class without being too restrictive on what community pharmacists can order and potentially exposing them to pricing fluctuations.

Dr. Wohleb moved that all of the calcium channel blockers are equally safe and efficacious, and, with the exception of nimodipine, there is no compelling reason to include any of the branded products on the PDL. Dr. Taylor seconded the motion. The motion passed unanimously by Duane Parke, Kort DeLost, Koby Taylor, Dr. Ward, Dr. Bushnell, Karen Gunning, and Jerome Wohleb.

Dr. Wohleb made a motion to suggest choosing one preferred product out of extended-release diltiazem, one preferred product out of extended-release verapamil, and one preferred product out of extended-release nifedipine to assure patient safety, and considering the MAC issue for cost savings. Dr. Bushnell seconded the motion. The motion passed with votes by Duane Parke, Kort DeLost, Dr. Bushnell, Karen Gunning, and Jerome Wohleb. Dr. Taylor and Dr. Ward voted against this motion, since it may create access to care problems for patients if a particular brand of generic is unavailable, and it could present problems for pharmacists in stocking the preferred generic.

The Committee declined to consider a motion for having Medicaid choose a preferred dihydropyridine.

Next Meeting Set for Friday, January 18, 2008.
Meeting Adjourned.

Minutes prepared by Jennifer Zeleny